ChoiceSpine, LLC
Kim Finch
Director of Regulatory Affairs
400 Erin Drive
Knoxville, TN 37919

August 15, 2019

Re: K191621
Trade/Device Name: ChoiceSpine Cervical Spacer System "Blackhawk", ChoiceSpine Cervical Interbody Spacer System "Ascendant", ChoiceSpine Cervical Interbody Spacer System "Ascendant PC", ChoiceSpine Intervertebral Fusion Device "Octane Straight", ChoiceSpine Intervertebral Fusion Device "Octane Straight PC", ChoiceSpine VEO Lateral Access & Interbody Fusion System, ChoiceSpine Octane A/T/P Spinal Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, OVE, MQP
Dated: July 15, 2019
Received: July 16, 2019

Dear Kim Finch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Melissa Hall
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191621

Device Name
ChoiceSpine Octane A/T/P Spinal Implant System

Indications for Use *(Describe)*

When used as a vertebral body replacement:
The ChoiceSpine Octane-A/T/P Spinal Implant is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Octane device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. The device may be used with autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and supplemental fixation to facilitate fusion.

When used as an intervertebral body fusion device:
The Octane-A/T/P Spinal Implant is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature, and have had at least 6 months of non-operative treatment. The device may be used with autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

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Expiration Date: January 31, 2017
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510(k) Number *(if known)*
K191621

Device Name
ChoiceSpine Cervical Interbody Spacer System "Ascendant PC"

Indications for Use *(Describe)*
The Ascendant PC Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Ascendant PC Cervical Spacer System is to be used autogenous and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

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510(k) Number *(if known)*
K191621

Device Name
ChoiceSpine Cervical Interbody Spacer System "Ascendant"

Indications for Use *(Describe)*
The Ascendant Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one-disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment.The Ascendant Cervical Spacer System is to be used with autogenous bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

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510(k) Number *(if known)*
K191621

Device Name
ChoiceSpine Cervical Spacer System "Blackhawk"

Indications for Use *(Describe)*
The BLACKHAWK™ Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The BLACKHAWK™ Cervical Spacer System is to be used autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

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510(k) Number *(if known)*

K191621

Device Name

ChoiceSpine Intervertebral Fusion Device "Octane Straight"

Indications for Use *(Describe)*

The Octane Straight Intervertebral Fusion Device is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least 6 months of non-operative treatment. The device system is designed for use with autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

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510(k) Number *(if known)*

K191621

Device Name

ChoiceSpine Intervertebral Fusion Device "Octane Straight PC"

Indications for Use *(Describe)*

The Octane Straight PC Intervertebral Fusion Device is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least 6 months of non-operative treatment. The device system is designed for use with autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

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See PRA Statement below.

510(k) Number *(if known)*
K191621

Device Name
ChoiceSpine VEO Laterial Access & Interbody Fusion System

Indications for Use *(Describe)*
The VEO™ Lateral Access & Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The VEO™ Lateral Access & Interbody Fusion System is designed to be used with autogenous and/or allogenic bone graft composed of cancellous and / or corticocancellous bone graft, and supplemental spinal fixation that is cleared for use in the lumbar spine.

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510(k) Summary

Date	August 12, 2019
Sponsor	ChoiceSpine, LLC 400 Erin Drive Knoxville, TN 37919
Phone Fax	865-246-3333 865-246-3334
Contact Person	Kim Finch, Director of Regulatory Affairs
Proposed Proprietary Trade Name	ChoiceSpine Cervical Spacer System “Blackhawk” ChoiceSpine Cervical Interbody Spacer System “Ascendant” ChoiceSpine Cervical Interbody Spacer System “Ascendant PC” ChoiceSpine Intervertebral Fusion Device “Octane Straight” ChoiceSpine Intervertebral Fusion Device “Octane Straight PC” ChoiceSpine VEO Lateral Access & Interbody Fusion System ChoiceSpine Octane A/T/P Spinal Implant System
Product Class	Class II
Classification Name	21 CFR 888.3080 - Intervertebral Body Fusion Device 21 CFR 888.3060 - Intervertebral Body Fixation Orthosis
Device Product Code	ChoiceSpine Cervical Spacer System “Blackhawk” (OVE) ChoiceSpine Cervical Interbody Spacer System “Ascendant” (ODP) ChoiceSpine Cervical Interbody Spacer System “Ascendant PC” (ODP) ChoiceSpine Intervertebral Body Fusion Device “Octane Straight” (MAX) ChoiceSpine Intervertebral Body Fusion Device “Octane Straight PC” (MAX) ChoiceSpine Lateral Access Interbody Fusion Device “VEO” (MAX) ChoiceSpine Vertebral Body Implant System “Octane A/T/P” (MAX), (MQP)
Purpose of Submission	The purpose of this submission is for ChoiceSpine Intervertebral Body Fusion Device Systems to gain clearance for the change in indications for use to allow the use of autogenous bone and/or allogenic bone graft comprised of cancellous and / or corticocanellous bone graft material.

Device Description

This submission includes 7 subject devices. The device descriptions for each are listed below:

The ChoiceSpine Octane Straight Intervertebral Fusion Device is an implant constructed of medical grade Polyetheretherketone, (PEEK-OPTIMA® LT1) as described by ASTM F2026. The implant incorporates ridges on the superior and inferior surfaces to resist expulsion. The device is open in the transverse plane to allow insertion of bone graft prior to placement, and fenestrated along the sides. The radiolucent PEEK-OPTIMA® material allows visualization of the defect site on radiography to assess bone growth, and incorporates tantalum markers conforming to ASTM F560 to permit verification of position. The Octane Straight Intervertebral Fusion Device is provided sterile for single use.

The ChoiceSpine Octane Straight PC Intervertebral Fusion Device is an implant constructed of medical grade Polyetheretherketone, (PEEK-OPTIMA® LT1) as described by ASTM F2026. The implant incorporates ridges on the superior and inferior surfaces to resist expulsion. The device is open in the transverse plane to allow insertion of bone graft prior to placement, and fenestrated along the sides. The radiolucent PEEK-OPTIMA® material allows visualization of the defect site on radiography to assess bone growth and incorporates tantalum markers conforming to ASTM F560 to permit verification of position. The device is plasma coated with commercial pure titanium (CPTi) per ASTM F1580. The Octane Straight PC Intervertebral Fusion Device is provided sterile for single use.

The BLACKHAWK™ Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK implant cage per ASTM F2026 with tantalum radiographic markers per ASTM F560, nitinol internal locking components per ASTM F2063 and two internal titanium alloy anchors (Ti-6Al-4V ELI) per ASTM F136. They are intended for use as interbody fusion devices and offered in a variety of heights, footprints, and lordotic angles to accommodate varying anatomical conditions. The devices feature a chamber intended to be filled with autogenous bone and or/allogenic bone graft material. They are used with two internal anchors that lock on deployment and provide additional fixation. The BLACKHAWK™ Cervical Spacer System is to be used with autogenous bone and or/allogenic bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

The Ascendant® Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK Optima® LT1 (polyetheretherkeytone) implant cage with tantalum radiographic markers. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints and lordotic angles to accommodate varying anatomical conditions. The device features an enclosed chamber intended to be filled with autogenous and or/allogenic bone graft material. The Ascendant® Cervical Spacer System is intended to be used with supplemental fixation (i.e., an anterior cervical plate).

The Ascendant™ PC Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK Optima® LT1 (polyetheretherkeytone) implant cage with CP titanium coating and tantalum radiographic markers. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints and lordotic angles to accommodate varying anatomical conditions. The device features an enclosed chamber intended to be filled with autogenous and or/allogenic bone graft material.

The VEO® Lateral Access & Interbody Fusion System is a multi-component system including instrumentation made of biocompatible materials such as Stainless Steel, Aluminum, and Radel R and implants made of Tantalum (ASTM F560) and PEEK (ASTM F2026) or Ti-6AI-4V ELI (ASTM F136).

The ChoiceSpine Octane®-A/T/P Spinal Implant is an implant constructed of medical grade Polyetheretherketone, (PEEK-OPTIMA® LT1) as described by ASTM F2026. The implant incorporates ridges on the superior and inferior surfaces to resist expulsion. The device is open in the transverse plain to allow insertion of bone graft prior to placement, and fenestrated along the sides. The radiolucent PEEK-OPTIMA® material allows visualization of the defect site on radiography to assess bone growth, and incorporates tantalum markers conforming to ASTM F560 to permit verification of position. The ChoiceSpine Octane Spinal Implant is provided sterile in three (3) styles:

- The Octane-T Spinal Implant, available heights of 7mm to 17mm, in 2mm increments;
- The Octane-P Spinal Implant, available in heights of 7mm to 17mm, in 2mm increments; and
- The Octane-A Spinal Implant, available in heights of 9mm to 19mm, in 2mm increments, and with a convex superior and inferior surface, angled at either 6° or 12° and in Small, Medium, or Large transverse profile.

Proposed Indications for Use

The Ascendant PC Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Ascendant PC Cervical Spacer System is to be used with autogenous and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

The Ascendant® Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one-disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment.

The Ascendant Cervical Spacer System is to be used with autogenous bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

The BLACKHAWK™ Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The BLACKHAWK™ Cervical Spacer System is to be used with autogenous bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

The Octane Straight Intervertebral Fusion Device is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least 6 months of non-operative treatment. The device system is designed for use with autogenous bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

The Octane Straight PC Intervertebral Fusion Device is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least 6 months of non-operative treatment. The device system is designed for use with autogenous bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.

The VEO® Lateral Access & Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The VEO™ Lateral Access & Interbody Fusion System is designed to be used with autogenous and/or allogenic bone graft composed of cancellous and / or corticocancellous bone graft, and supplemental spinal fixation that is cleared for use in the lumbar spine.

	The ChoiceSpine Octane-A/T/P Spinal Implant System: **When used as a vertebral body replacement**: The ChoiceSpine Octane®-A/T/P Spinal Implant is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture), to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Octane device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. The device may be used with autogenous bone and/or allogenic bone graft composed of cancellous and / or corticocancellous bone graft, and supplemental fixation to facilitate fusion. The ChoiceSpine Octane-A/T/P Spinal Implant System: **When used as an intervertebral body fusion device**: The Octane®-A/T/P Spinal Implant is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD,) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature, and have had at least 6 months of non-operative treatment. The device may be used with autogenous bone and/or allogenic bone graft composed of cancellous and / or corticocancellous bone graft, and with supplemental fixation systems cleared for use in the lumbosacral spine.
Materials	The implants are made from either titanium alloy (Ti-6AI-4V ELI per ASTM F3001 or F1472) or polyetheretherketone (PEEK-Optima) per ASTM F2026 with tantalum markers per ASTM F560.
Non-Clinical Testing	All subject components have been cleared and therefore do not present a new mechanical worst-case and no non-clinical testing is needed.
Predicate Device	**Primary Predicate:** Nexxt Spine, LLC MatrixxTM System (K171140) **Additional Predicate**: ChoiceSpine TOMCAT™ Cervical Spacer System (K170953) **Additional Predicate:** ChoiceSpine Blackhawk™ Cervical Spacer System (K171489) **Additional Predicates:** ChoiceSpine Ascendant Cervical Spacer System "Ascendant" (K141129), ChoiceSpine Cervical Spacer System "Ascendant PC" (K150130) **Additional Predicate:** SeaSpine Spacer System – Hollywood, Hollywood VI, Ventura, Pacifica (K173260), **Additional Predicates:** ChoiceSpine Intervertebral Fusion Device "Octane StraightPC" (K150152), ChoiceSpine Intervertebral Fusion Device "Octane Straight" (K130434), ChoiceSpine VEO™ Lateral Access interbody Fusion Device (K123997), and ChoiceSpine Octane A/T/P™ Vertebral Body Implant System (K082270)

Substantial Equivalence	Nexxt Spine, LLC Matrixx TM System (K171140).
Substantial Equivalence Conclusion	The implants proposed in this submission are similar to the predicates in principle of operation, materials, indications for use, biocompatibility, manufacturing and post processing steps, stabilization methods, sterilizations method, anatomic location and approach, product classification and product codes. The only differences are the indications for use for the subject devices indicate the use of autograft bone and the primary predicates allow with autograft bone and/or allogenic bone graft composed of cancellous and / or corticocancellous bone graft. Both the subject devices and predicate devices require supplemental fixation. After considering all similarities and differences to the predicate devices, the subject device has shown to be equivalent when compared to the predicate devices in safety, effectiveness, and performance.